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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/111,193	7/7/98	RAGHUANT	H ALLIA143

EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
1644	20

DATE MAILED: 09/25/01

022855
HM12/0925
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Please find below and/or attached an Office communication concerning this application or proceeding.

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To:	LEEVI OLIVIER	**Fax:**	619-235-0176
From:	GOIGA DUCKETT	**Date:**	11/7/01
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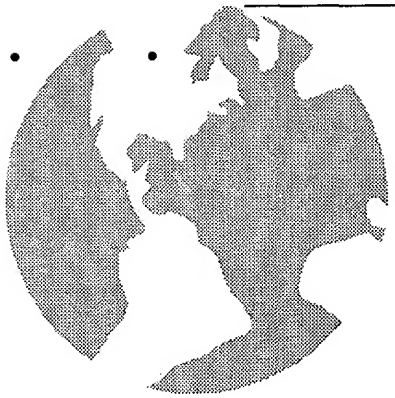

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To:	OLIVIER LEEVI	Fax:	619-235-0176
From:	GOIGA DUCKETT	Date:	11/2/01
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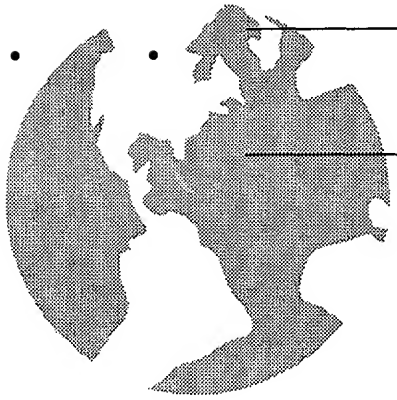

Office Action Summary

Application No.	Applicant(s)
09/111,123	Zaghouani et al.
Examiner	**Art Unit**
Patrick J. Nolan	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 5, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above, claim(s) *8-20* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Part III DETAILED ACTION

1. Claims 1-20 are pending.

2. Claims 8-20 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, for reasons set forth in Paper No. 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-7 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bona et al. (U), in view of Kuchroo et al. (6), (IDS) and Karin et al. (X), of record.

Applicant's arguments filed 7-5-01 have been fully considered but are not found persuasive.

Applicant argues that there was no motivation to combine the teachings of Kuchroo et al., and Karin et al., with the teaching of Bona et al., since Bona et al., teaches the use of antigens in their immunoglobulin delivery system and Kuchroo et al., and Karin et al., teach the use of altered peptide ligands.

However, one of skill in the art would clearly recognize that altered peptide ligands are antigens since they are bound by T cell

receptors and MHC class II molecules are inhibit activated T cells. Furthermore Applicant is guided towards In re Rosselet, 146 USPQ 183,(CCPA 1965), which recognized that ※The test for obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them.※ In the instant case Bona et al., taught that the immunoglobulin delivery system would be useful "to express other biologically important epitopes such as tumor antigens, oncogenes or self antigens which can be used in the antitumor therapy or the therapy of autoimmune diseases. In the later cases, it is possible that the IG bearing epitopes of self antigens will be more efficient for peptide competition therapy envisioned as a novel immunotherapeutic approach of autoimmune diseases" (page 29, in particular). Since Kuchroo et al., and Karin et al., taught the use of altered peptide ligands in the treatment of autoimmune diseases wherein said peptides work by peptide competition therapy, one of skill in the art familiar with peptide competition therapy would have been motivated to incorporate the altered peptide ligands in the immunoglobulin delivery system taught by Bona et al., for more efficient peptide delivery and longer lasting peptide activity as taught by Bona et al. In addition the claimed invention would be expected to meet the additional limitation of preventing T cell activation since the Kuchroo et al., and Karin et al., already teach that property for the APL in T cell activation assay.

The declaration under 37 CFR 1.132 filed 7-5-01 is insufficient to overcome the rejection of claims 1-17 based upon Bona et al., in view of Kuchroo et al., and Karin et al., as set forth in the last Office action.

In addition Applicant's arguments directed to the declaration and towards unexpected results are found non-persuasive because a showing of unexpected results must convey to scope of the claimed invention. Presently, the scope of Applicant's claimed invention is drawn towards the treatment of any autoimmune disease by administering any T cell receptor antagonist in any immunoglobulin or portion thereof that is capable of binding to an Fc receptor and being endocytosed by an antigen presenting cell. However, the showing of "unexpected" result is limited to the treating of neonatal EAE mice, induced to have EAE at 6-8 weeks, with an altered PLP peptide inserted into the CDR3 region of a complete immunoglobulin protein and testing for disease remission for 120 days. This result does not convey to the full scope of the claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the

term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-7 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 of copending application Serial No. 08/779,767. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention claimed in claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 of copending application Serial No. 08/779,767 are composition claims claiming overlapping subject matter of the invention claimed, product claims, in claims 1-7, of the instant application.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has not traversed this rejection so it is maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the

advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
September 24, 2001